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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/888,057 07/03/97 STICE

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021839 HM12/0516
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EXAMINER

CROUCH, D

ART UNIT

PAPER NUMBER

1632

13

DATE MAILED:

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/888,057

Applicant(s)
Stice et al.

Examiner
Deborah Crouch

Group Art Unit
1632



☒ Responsive to communication(s) filed on Feb 4, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle* 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three (3) month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-82 is/are pending in the applicat

Of the above, claim(s) 36-45, 66-70, and 77 is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-35, 46-65, 71-76, and 78-82 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Applicant's arguments filed February 4, 2000 in paper no. 12 have been fully considered but they are not persuasive. The amendment has been entered. Claims 1-35, 46-65, 71-76 and 78-82 are examined in this office action.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-17, 24, 25, 61, 63 and 79-82 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 103-126 of allowed of U.S. Patent No. 08/781,752. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are obvious over the claims of '752. The instant claims are methods of cloning pigs and methods of cloning transgenic pigs. The claims of '752 are to methods of cloning mammals and methods of cloning transgenic mammals, with a specific claims to pig. Thus the instant claims are obvious over the claims of '752 as the ordinary artisan having claims 103-126 would have sufficient teachings and motivation to produce the cloned pigs as instantly claimed.

These are provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant has requested that this rejection be held until allowable subject matter is determined.

Claims 1-17,24,25,29,30,32,34,46-48,50,52,54,55,57,59,61-63,78,79 and 81 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods where the differentiated donor cell or the donor nucleus is from a differentiated cell that has been expanded in culture, does not reasonably provide enablement for an differentiated cell. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are drawn to a method of cloning a pig comprising inserting a differentiated pig cell or cell nucleus, a differentiated pig cell or cell nucleus wherein a DNA sequence is inserted, removed or modified, a pig CICM cell or cell nucleus, into an enucleated mammalian oocyte, activating the nuclear transfer unit, culturing the activated nuclear transfer unit to greater than the 2-cell stage and transferring the cultured nuclear transfer unit to a host mammal, a method of producing a CICM cell line comprising inserting a differentiated pig cell or cell nucleus, or a differentiated pig cell or cell nucleus wherein a DNA sequence is inserted, removed or modified, into an enucleated mammalian oocyte, activating the nuclear transfer unit, culturing the activated nuclear transfer unit to greater than the 2-cell stage and culturing cells obtained from the nuclear transfer unit, a method of producing a pharmaceutically active protein expressing a transgenic pig offspring, and methods of making chimeric pigs.

Applicant argues that in the parent a declaration under 37 CFR 132 was filed in the parent file 08/781,752. Applicant explains that the declaration stated that the claimed invention is a pioneering invention, and that the ability to clone a mammal using a somatic or differentiated was surprising. This argument is not persuasive.

If applicant wishes the examiner to consider the declaration filed in the parent case to be considered, then a copy should be filed. Papers filed in a separate serial number are neither transferred nor considered by the office. Any paper to be considered should be filed in each case

such consideration is desired. No consideration of scope can be given unless evidence is before the examiner. Further, the double patenting rejection merely states that the claims are of obvious subject matter. The instant claims certainly are broader than those of the allowed parent, but as the method of the allowed parent is specifically disclosed in the instant specification, that method is obvious as one would determine that the allowed method was within the scope of the "differentiated cell" of the instant claims. However, in view of applicant's arguments, a scope rejection has been instituted, based on the claims in the allowed parent '752.

Applicant argues that in the parent filed supporting documents were filed that indicate that the instant method of cloning is generically applicable, and not limited to any particular species. This argument is not persuasive.

Any mention of a particular species is because the instant claims, both original and amended, are drawn specifically to pigs. This is a limitation instituted by applicant and not by the examiner. If broader claims are wanted, then it is up to applicant to point out and claim that which they consider to be the invention.

Applicant argues that uses for chimeric and transgenic pigs, where the donor cell nucleus is genetically modified, the cloned pigs could be used as donors in xenotransplantation procedures. Applicant argues that the claimed method is a simplification of procedures for the production of transgenic pigs as one could select a cell which sufficiently expresses the transfected gene prior to cloning procedures. Applicant argues that this removes any unpredictability regarding the expression of transgenes in transgenic animals. Applicant argues that this directly relates to the production of transgenic pigs as organ donors. These arguments are not persuasive.

There is no evidence on record that expression by a cell in vitro predicts to any degree the level of expression in vivo or the production of any particular phenotype developed by a

cloned transgenic pig. Whereas, there maybe some level of detectable expression, there is no prediction that in vitro expression levels equates to any particular phenotype.

Applicant argues that other uses of clone animals would be apparent from the multitude of references related to animal cloning to determine other uses. This is not persuasive.

The specification is to be complete. Any uses contemplated by applicant are to be disclosed. The artisan is not supposed to have determine what uses applicant intends, rather they are supposed to be given in the specification. necessary. However, enablement must be supplied by the specification. The CAFC has stated that "the specification, not knowledge in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement". See *Genetech inc v. Novo Nordisk A/S* 42 USPQ2d 1001, at 1005.

The rejection of claims 29,47,48,50,52,54,55,57,59 and 78 under 35 U.S.C. 112, second paragraph, in previous office action has been overcome by applicant's amendments to the claims.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 19,20,27,28,65 and 71-75 remain rejected under 35 U.S.C. 102(b) as being clearly anticipated by Cisneros et al (1996) J. Animal Science 74, 925-933 for reasons of record.

Claims 18,26 and 64 remain rejected under 35 U.S.C. 102(b) as being clearly anticipate by Cukrowska et al (1996) Immunology 87, 487-492 for reasons of record.

Claims 21-23 and 76 remain rejected under 35 U.S.C. 102(b) as being clearly anticipated by Fodor et al (1994) Proced. Natl. Acad. Sci. 91, 11153-11157 for reasons of record.

Claim 31 remain rejected under 35 U.S.C. 102(b) as being clearly anticipated by Strojek et al (1990) Theriogenology 33, 901-913 for reasons of record.

Claim 35 remain rejected under 35 U.S.C. 102(b) as being clearly anticipated by Brameld et al (1995) J. Endocrin. 146, 239-245 for reasons of record.

Claims 49, 51 and 53 remain rejected under 35 U.S.C. 102(b) as being clearly anticipated by Onishi et al (1994) Biology of Reproduction 51, 1069-1075 of record.

Claims 56, 58 and 60 remain rejected under 35 U.S.C. 102(b) as being clearly anticipated by Rosengard et al (1995) Transplantation 59, 1325-1333 for reasons of record.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 33 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Strojek et al (1990) Theriogenology 33, 901-913 for reasons of record.

Applicant argues that the claimed pig embryos, fetuses and offspring, pigs and transgenic and chimeric derivatives of pig embryos, fetuses and offspring, and pigs have a unique genotype that would not be found in pigs, pig embryos and pig fetuses that were not generated by cloning. Applicant argues that such pigs, pig embryos and pig fetuses can be distinguished because they have an identical genotype of a prior existing pig, pig embryos, pig fetus or differentiated pig cell. Applicant argues that they have amended the claims to state this genotype identity. These arguments are not persuasive.

The amendment of the claims to state that the product is genetically identical to a prior existing pig does not overcome the rejections of record. The determination of patentability in a

product-by-process claim is based on product, its characteristics, features and properties. The parentage of the pigs, pig embryos, pig fetuses, pig offspring, pig CICM cell lines, and differentiated pig cells does not effect the pigs, pig embryos, pig fetuses, pig offspring, pig CICM cell lines, and differentiated pig cells of the claims. Any alteration provided by the process must be directly on the product, in this case the pigs, pig embryos, pig fetuses, pig offspring, pig CICM cell lines, and differentiated pig cells. There is no evidence of record, and none has been argued, that indicates that the cloning method provides any patentable alteration to the pigs, pig embryos, pig fetuses, pig offspring, pig CICM cell lines, and differentiated pig cells. By analogy, the amended claims in the instant applicant are similar to claims to a protein, where the protein is claimed to be isolated from tissue culture media after recombinant expression in vitro, and the prior art discloses the isolation of the protein from tissue sources. The source of the protein does not affect the characteristics, features or properties of the protein. Furthermore, as applicant is not claiming any particular genotype of pigs, pig embryos, pig fetuses, pig offspring, pig CICM cell lines, and differentiated pig cells, the claims read on any prior existing pigs, pig embryos, pig fetuses, pig offspring, pig CICM cell lines, and differentiated pig cells. The cited prior art teaches such prior existing pigs, pig embryos, pig fetuses, pig offspring, pig CICM cell lines, and differentiated pig cells and is relevant to the claims regardless of how the pigs, pig embryos, pig fetuses, pig offspring, pig CICM cell lines, and differentiated pig cells were made.

Claims 80 and 82 would be allowable if written in independent form.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the

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mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is (703) 308-1126.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

The fax number is (703) 308-4242.

Deborah Crouch

DEBORAH CROUCH
PRIMARY EXAMINER
GROUP 1800-1630

Dr. D. Crouch
May 15, 2000